

Substitute Specification--Clean Copy

Flexible Vertebral Linking Device**FIELD**

[0001] The invention relates to a posterior flexible vertebral linking device which works in tension, compression and flexion, and which dampens all mechanical stresses. This device has operational advantages that will be described.

BACKGROUND

[0002] Many posterior vertebral attachment units exist which rigidize a certain number of vertebrae by depriving them of any mobility, thus containing all mechanical stresses. However, the first vertebra adjacent to this rigidized block of vertebrae remains mobile and, consequently, there is an abrupt discontinuity in movement between the rigid block and this free vertebra which very often generates a very high stress in the linking elements. The result is an acceleration of the degeneration of this level (the interface between the adjacent vertebrae and the vertebrae comprising part of the rigidized block).

[0003] This problem was only partially solved by semi-rigid systems conceived to create an intermediate rigidity between the mobile vertebrae and the fixed vertebrae. These prior art systems present primarily one of two disadvantages, either they work only in tension or they work in compression with a thrust in tension.

[0004] As for those that work only in tension: this is the case of all the devices based on artificial ligaments. These systems have little elasticity and leave the care to regulate, in particular, the tension, to the skill of the operator, thus making the

Substitute Specification--Clean Copy

mechanical characteristics in the operating mode of interest (tension/compression) haphazard.

[0005] Further, those devices that work in compression with a thrust in tension are ineffective when dealing with displacements in tension.

[0006] In either case, none of the known devices entirely solves the problem which is posed, namely, damping the mechanical stresses existing in tension/compression and flexion to which a moving vertebra is subjected.

[0007] Patent Application EP 0576 379 A1 proposes a shock absorber which seems to approach most closely at least from the point of view of the general concept of this invention. This patent describes a uni-axial shock absorber working only in compression while playing the part of an abutment which opposes any displacement of the piston beyond a given value.

[0008] The invention of EP 0576379 A1 deals with the exponential limitation of the displacement, which is a completely different problem as that of the present invention.

[0009] French Patent application No. 0,012,998, describes and claims a flexible and cast solid vertebral linking device functioning in a multidirectional way. This prior art reference does not solve exactly the same problem as that of the present invention due to its different means and functions.

SUMMARY

[0010] The invention concerns a flexible intervertebral linking device that meets the needs identified above. The device (1) utilizes two sets of structures. A first

Substitute Specification--Clean Copy

structure (11) is a rigid structure (110, 112, 114, 116) preferably made of biocompatible metallic materials providing the device with good mechanical resistance by integral load transmission without deformation. A second structure (12) is a flexible or damping structure (121 and 122) made of biocompatible viscoelastic materials, permitting repeated elastic deformations, the combination of the two structures providing the device with both resistance and mechanical stress damping of forces to which it is subjected, with the purpose of compensating for any deficiency in the flexibility of certain anatomical links of the human body.

[0011] In an advantage, the surgeon can choose in a precise way the desired working method: tension/compression or flexion, or the combination of the two working methods, so as to avoid any contact between the articular facets.

Substitute Specification--Clean Copy

BRIEF DESCRIPTION OF THE DRAWINGS

- [0012] FIGS. 1A and 1B are perspective views (two alternative embodiments) of the device operating in tension, compression and flexion.
- [0013] FIGS. 2A and 2B are longitudinal cross-sectional views of two alternative embodiments of the invention.
- [0014] FIG. 3 is an exploded view of the invention.
- [0015] FIG. 4 is a perspective view of the invention for operation only in tension/compression.
- [0016] FIG. 5 is a cross-sectional view of the invention operating only in tension/compression.
- [0017] FIGS. 6 to 11 are perspective views depicting the individual parts of the invention.
- [0018] FIG. 12 is a perspective view of another component for operation in the tension/compression mode.
- [0019] FIG. 13 is a side, cross-sectional view of an alternative of the device working along two axes.
- [0020] FIGS. 14 to 17 are perspective views of four forms of the mobile end of other embodiments of the invention.
- [0021] FIG. 18 is a side, cutaway view of the invention in place in a patient.

Substitute Specification--Clean Copy

DETAILED DESCRIPTION

[0022] The device 1 utilizes two sets of structures. A first structure 11 a rigid structure manufactured out of preferably metal, biocompatible material ensuring a good mechanical resistance of the device by completely transmitting the forces.

[0023] A second structure 12 is a flexible or damping structure manufactured out of viscoelastic biocompatible materials, supporting the repeated elastic strain. It is the combination of these two structure which makes the operation of the invention possible.

[0024] The first structure 11 includes four mechanical structures 110, 112, 114, 116 which have the function of transmitting stresses to which the device 1 is subjected without deformation.

[0025] The mechanical structure 110 is made up of a mechanical rod 111, one of its ends being surmounted by a circular plate 113b connected to the rod 111 with a broad joining radius 113a, and the assembly being able to slide in the cavity of the structure 114 which encloses a visco-elastic element 121.

[0026] The mechanical structure 112 is a cap provided with a thread 117 allowing for the fixing of the structure 112 on structure 114; the structure 112 has a shoulder area 118 which encloses a viscoelastic-centering ring 121 between the plate 113b.

[0027] The mechanical structure 114 is made up of two hollow cylinders, one of which is tapped to allow the fixing of a rod 116 with a threaded end. The mechanical structure 110 and 116 will be fixed on the vertebrae to permit the functioning of the device 1.

[0028] The second structure 12 is made up of two viscoelastic components 121 and 122.

Substitute Specification—Clean Copy

- [0029] The centering ring 121 preferably allows the rod 111 to slide in its center.
- [0030] The second component 122 is a disc of viscoelastic material. These two centering rings 121 and 122 can undergo compressive stresses which may not be uniformly distributed. They are formed to resist many cyclic fatigue stresses without breaking. Compressive tests have been performed which verify that the components 121 and 122 are able to undergo these tests of elastic deformation as many times as necessary.
- [0031] The selected material is preferably a biocompatible polyurethane; thanks to their integration inside mechanic components 110, 112, 114, 116, the viscoelastic elements 121 and 122 are protected by the preceding mechanical structures from the aggressive environment of the human body, which avoids in particular the formation of fibers around these components which could deteriorate the viscoelastic properties of the material and consequently disturb the correct operation of device 1.
- [0032] This device 1 makes possible the damping of the stresses in tension/compression and flexion which it undergoes by the intermediary of rods 110 and 116. This function is assured owing to the fact that component 112 has a sufficiently broad opening 119 to allow a clearance of rod 111 and that there is a functional allowance between plate 113 and the hollow body of component 114; the shoulder area 118 serves as a stop and maintains in its housing the viscoelastic element 121 thus constrained.
- [0033] If one wishes to work in a uni-axial mode of tension/compression, component 112 is replaced by another component 115 equipped with threads 117,

Substitute Specification--Clean Copy

which includes a cap 115c, whose opening 119 is of a diameter which corresponds to the diameter of the rod 110 and which is elongated with a rod guide 115a.

[0034] This device 1 is thus able to react dynamically to the applied stresses.

Note that it is essential that structure 114 comprises a bore 114a to allow for low friction guidance of rod 110 in the aforementioned component 114.

[0035] The adjustment of the diameter of the viscoelastic centering rings 121 and 122 must be selected with precision to enable them to be crushed freely until a stress threshold is reached, this threshold corresponding to a point of contact of the bore 114a of component 114.

[0036] An alternative to the structure 11 includes metal structures having the same functions as the structures 110, 112, 114, 116, but the assembly of these three parts (110,130, 131) having a lower threshold than that of the structures previously described (see FIG. 2).

[0037] The rod 131 is fixed at its cap 130 by the intermediary of a thread located on shoulder 132 of the rod.

[0038] In this alternative embodiment, the possibilities of displacement of rod 110 subjected to the stresses in flexion are enabled by play 119 located between cap 130 and rod 110.

[0039] For a uni-axial operation of device 1, it is preferable to use components 110,112, 114, 116 which provide a better guidance of rod 110. If small overall dimensions are needed, components 110, 130, 131 may be preferably used.

[0040] Device 1 is able to function with rods 110 and 131 moving on convergent axes (FIG. 13) with a small angle of displacement and according to given clearances.

Substitute Specification–Clean Copy

[0041] The structure 12 is therefore comprised of two visco-elastic components 141 and 142. Note that the rod 110 has a flange 110' on its end. The component 141 is a cylinder of visco-elastic biocompatible material whose face in contact with the flange 110' is inclined. The component 142 is a centering ring whose face in contact with the back of the flange 110' is inclined.

[0042] The structure 11 (rigid means) is identical to the previous one that is described above, the orifice 119 being however eccentric depending on the chosen angle. The shape of orifice 119 is defined depending on the clearances allowed with the rod 110.

[0043] The rod 110 is thus able, thanks to these new technical characteristics, to function in tension/compression with a given angle with respect to the rod 116 or the rod 131 in the case in which the 119 orifice is eccentric and adjusted to the rod 116 or 131(see FIG. 14).

[0044] The rod 110, forming an angle with respect to the rod 116 or 131 (the case in which the 119 orifice is oblong and eccentric), can in this case function equally well in tension/compression as in lateral flexion. (see FIG. 15).

[0045] The rod 110 can function in tension/compression and in flexion following a preferred axis which can be, for instance, in the sagittal plane of the spinal column, and this one on the one side and one the other side of a given position of the rod 110 which, at rest, forms an angle with the rod 116 or the rod 131, this also being the case where the component 119 is oblong or eccentric, (FIG. 16).

Substitute Specification--Clean Copy

[0046] Finally, the rod 110 can function in tension/compression and in flexion in all directions, forming an angle, as against the rod 116 or 131 in case the orifice 119 is eccentric or larger than the diameter of the rod 110 (see FIG. 17).

[0047] Multiple variations and modifications are possible in the embodiments of the invention described here. Although certain illustrative embodiments of the invention have been shown and described here, a wide range of modifications, changes, and substitutions is contemplated in the foregoing disclosure. In some instances, some features of the present invention may be employed without a corresponding use of the other features. Accordingly, it is appropriate that the foregoing description be construed broadly and understood as being given by way of illustration and example only, the spirit and scope of the invention being limited only by the appended claims.